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Patent Application

for

AN INTEGRATED SYSTEM FOR CORRECTION OF REFRACTIVE ERROR OF  
THE HUMAN EYE USING AN ABLATABLE CORNEAL INLAY

by

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**Related Applications**

**[0001]** This application is related to U.S. Application Serial No. 09/758,263, filed January 12, 2001, and U.S. Application Serial No. 09/797,177, filed March 2, 2001, the entire contents of both of which are herein incorporated by reference.

**Field of the Invention**

**[0002]** The present invention relates to a system and method for correcting the refractive error in the cornea of the eye. More particularly, the present invention

relates to a system and method for correcting the refractive error in the cornea of the eye using robotic arms to assist in forming a flap in the surface of the cornea and placing a corrective lens under the flap.

### **Background of the Invention**

**[0003]** A conventional method for correcting the refractive error in a cornea is keratophakia, i.e., implantation of a lens inside the cornea. Keratophakia uses an implant, which is placed into the cornea approximately equidistant from the exterior surface of the cornea and the interior surface. The procedure is usually done by first preparing a lens from corneal donor tissue or synthetic material using a cryo-lathe. The lens is implanted by removing a portion of the cornea with a device called a microkeratome, and the tissue is sutured back into place over the lens. However, there can be problems when microkeratomies are used for cutting the cornea. First, irregular keratectomies or perforations of the eye can result. Second, the recovery of vision can be rather prolonged.

**[0004]** Another surgical technique exists that uses a femtosecond laser to separate layers inside the stroma, at least two-thirds of the distance from the top surface of the cornea to the inside of the eye. An incision is made to access this area and a solid inlay is inserted to help correct myopia in the eye. However, by separating the layers in the bottom two-thirds of the stroma, it is difficult to access the separated area to insert the inlay and virtually impossible to change or modify the inlay without another extensive surgical procedure. This procedure also requires making an incision, which is parallel to the visual axis and is limited in the lateral direction by a maximum size of 0.3 mm, to encase a relatively rigid inlay that forces the tissue in the lateral direction.

**[0005]** Additional surgical techniques exist that use ultraviolet light and short wavelength lasers to modify the shape of the cornea. For example, excimer lasers, such as those described in U.S. Patent No. 4,840,175 to Peyman, which emit pulsed ultraviolet radiation, can be used to decompose or photoablate tissue in the live cornea

so as to reshape the cornea. The entire content of U.S. Patent No. 4,840,175 is incorporated by reference herein.

**[0006]** Specifically, the Peyman patent discloses the laser surgical technique known as laser in situ keratomycosis (LASIK). In this technique, a portion of the front of the live cornea can be cut away in the form of a flap having a thickness of about 160 microns. This cut portion is removed from the live cornea to expose an inner surface of the cornea. A laser beam is then directed onto the exposed inner surface to ablate a desired amount of the inner surface up to 150-180 microns deep. The cut portion is reattached over the ablated portion of the cornea and assumes a shape conforming to that of the ablated portion. Additionally, in the Lasik procedure, a femtosecond laser can be used to cut and separate the flap.

**[0007]** However, because only a certain amount of cornea can be ablated without the remaining cornea becoming unstable or experiencing outbulging (eklasisa), this technique may not be especially effective in correcting very high myopia. That is, a typical cornea is on average about 500 microns thick. The laser ablation technique generally requires that at least about 250 microns of the corneal stroma remain after the ablation is completed so that instability and outbulging do not occur.

**[0008]** Additional methods for correcting the refractive error in the eye include inserting an implant between layers of the cornea. Generally, this is achieved using several different methods. One method involves inserting a ring between layers of the cornea, as described in U.S. Patent No. 5,405,384 to Silvestrini. Typically, a dissector is inserted in the cornea and forms a channel therein. Once it is removed, a ring is then inserted into the channel to alter the curvature of the cornea. In another method, a flap can be created in a manner similar to the LASIK procedure, and a lens can be inserted under the flap, as described in U.S. Patent No. 6,102,946 to Nigam. A further method involves forming a pocket using an instrument, and inserting an implant into the pocket, as described in U.S. Patent No. 4,655,774 to Choyce. The entire contents of U.S. Patent Nos. 4,655,774, 5,405,384 and 6,102,946 are incorporated by reference herein.